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The social phobia psychotherapy research network

Submission date	Recruitment status	[X] Prospectively registered
22/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/07/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/08/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The social phobia psychotherapy research network

Acronym
SOPHO-NET

Study objectives
Differential efficacy of short-term psychodynamic psychotherapy (STPP) and cognitive-behavioral therapy (CBT) in social phobia therapy - named hypothesis A1

The first add-on study (named C1) of this multicentre trial will be studying genetic polymorphisms in patients with social phobia who are treated with STPP and CBT.

The second add-on study (named C2) of this multicentre trial will be studying the neural functional and structural changes in patients with social phobia who are treated with STPP and CBT.

The third add-on study (named C3) of this multicentre trial will be studying the attachment characteristics as differential predictors of treatment outcome in 128 patients with social phobia who are treated with STPP and CBT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty of the University of Goettingen, 06/12/2006

Study design
Randomized controlled multicenter trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Social phobia (social anxiety disorder)

Interventions
Manualized short-term psychodynamic psychotherapy (STPP) versus manualized cognitive-behavioral therapy (CBT)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
For A1, primary outcome is no diagnosis of SP according to the SCID-I DSM-IV and the Liebowitz Social Anxiety Scale

For C1, the primary outcome will be, that the psychotherapy outcome is associated with genetic variation in the serotonin transporter (SERT) gene (directed: L12 higher pre-post difference in the Liebowitz Social Anxiety Scale [LSAS])

For C2, primary outcomes will include normalisation of neural structural and functional abnormalities after successful treatment

For C3, primary outcomes will be whether patients reveal a secure organized attachment; representation will reach a better outcome than those with insecure features and\or disorganized states of mind

Key secondary outcome(s))
For A1, secondary outcomes will include:
1. Social anxiety (Social Phobia and Anxiety Inventory [SPAI])
2. Depression (Beck Depression Inventory [BDI])
3. Interpersonal problems (IIP)
4. Self-image
5. Quality of life or social functioning (short-form-12 questionnaire [SF-12])
6. Costs and utilities of the treatments

For C1, the secondary outcome will be, that the severity of social phobia is linked with genetic variation in SERT gene (directed: S10 higher LSAS at baseline)

For C2 secondary outcome will include specificity of neural structural and functional abnormalities in social phobia

For C3, secondary outcome will include whether a self-reported attachment will significantly change after successful therapy indicating increased security. This will be tested by using the Experiences in Close Relationships-Revised (ECR-R) instrument within the entire sample (n = 512)

Completion date
01/10/2009

Eligibility

Key inclusion criteria
1. Diagnosis of social phobia (SP) according to the Structured Interview for Diagnostic and Statistical Manual of Mental Disorders - fourth edition [SCID-I DSM-IV]) and primary diagnosis of social phobia according to the Liebowitz Social Anxiety Scale >302
2. Aged 18 to 59 versus 60 to 70 years
4. Participants must be made up of 60% women; 40% men

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Psychotic disorder
2. Risk of self-harm
3. Acute substance related disorder
4. Personality disorders except for cluster C
5. Organic mental disorder
6. Severe medical conditions
7. Concurrent psychotherapeutic or psychopharmacological treatment

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Germany

Study participating centre
von Sieboldstrasse 5
Goettingen
Germany
37075

Sponsor information

Organisation
Ministry for Development and Research (Bundesministerium für Bildung und Forschung [BMBF]) (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/12/2013		Yes	No
Results article	results	19/01/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes